

PATENT COOPERATION TREATY

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REC'D 28 AUG 2007

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 59849 PCT (FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US04/41921	International filing date (day/month/year) 10 December 2004 (10.12.2004)	Priority date (day/month/year) 12 December 2003 (12.12.2003)
International Patent Classification (IPC) or national classification and IPC IPC: G01 N 33/53,33/567;C07K 16/18(2006.01),7/64(2006.01) USPC: 435/7.2;530/317,388.25		
Applicant GOVT. OF THE US AS REPRESENTED BY THE SECRETARY, DEPT. OF HEALTH AND HUMAN SERVICES		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of ___ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 22 March 2007 (22.03.2007)	Date of completion of this report 03 August 2007 (03.08.2007)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Parithosh K. Tungaturthi Telephone No. (571) 272-1600 <i>Janie Ford for</i>

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US04/41921

I. Basis of the report1. With regard to the **elements** of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-101 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the claims:
pages 102-110, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the drawings:
pages 1-10, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US04/41921**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>1-78</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-78</u>	NO
Industrial Applicability (IA)	Claims <u>1-78</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS**CITATIONS:**

PGPUB 20030235868 (HOOGENBOOM et al) 25 December 2003, Abstract and detailed description of the inventio, in particular.

US 5,861,381 (CHAMBON et al) 19 January 1999, Abstract and detailed description of the invention, in particular.

PGPUB 20040054137 (THOMSON et al) August 4th, 2003, Abstract and the brief description the invention, in particular.

PBPUB 20050042209 (KUFE et al) Priority date September 11th, 2000, Abstract and Brief description of the invention in particular.

EXPLANATIONS:

Claims 1-78 lack an inventive step under PCT Article 33(3) as being obvious over Chambon et al (U.S. Patent 5,861,381; date issued January 19, 1999) and in view of Hoogenboom et al (PGPUB 20030235868; Priority claimed April 22, 2002)

The instant claims are summarized as isolated nucleic acid molecule which encodes an agonist polypeptide antigen derived from MUC-1, wherein the agonist polypeptide stimulates an immune response, a method for generating an immune response to a MUC-1 tumor antigen comprising administering an isolated nucleic acid molecule. A method of treating a subject and a method of screening a molecule to generate an immune response to a MUC-1 to a tumor antigen.

Chambon et al teach a pharmaceutical composition comprising SEQ ID NO:1,2,3,4,5,6,7,8, 9, 10 of the instant application intended for the curative treatment or the prevention of a malignant tumor, more especially of a carcinoma and most especially of a breast cancer a method of screening a molecule to generate an immune response to a MUC-1 to a tumor antigen. Chambon et al does not teach the method of identifying the molecule to generate an immune response to a MUC-1 to a tumor antigen.

Hoogenboom et al teach agonist polypeptide antigen derived from MUC-1 wherein the agonist polypeptide stimulates an immune response and a method of identifying a molecule that has the ability to generate an immune response to MUC-1.

It would have been obvious to combine the teachings of Chambon et al and Hoogenboom et al a method for generating an immune response to a MUC-1 tumor antigen comprising administering an isolated nucleic acid molecule, in addition to producing a method of treating a subject and a method of screening a molecule to generate an immune response to a MUC-1 to a tumor antigen.

Therefore, claims 1-78 lack an inventive step under PCT Article 33(3) as being obvious over Chambon et al and in view of Hoogenboom et al.